

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) P1818	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 [37 CFR 1.8(a)] On <u>November 14, 2006</u> Signature <u>/Kimberly Melvin/</u> Type or printed Name <u>Kimberly Melvin</u>		Application Number 10/674,296	Filed September 29, 2003
		First Named Inventor: THORNTON, Ronan	
		Art Unit 3738	Examiner PRONE, Christopher
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <input type="checkbox"/> applicant/inventor <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96). <input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>35,268</u> <input type="checkbox"/> attorney or agent under 37 CFR 1.34. Registration number if acting under 37 1.34 _____ </div> <div style="width: 35%; text-align: right;"> <u>/Catherine C. Maresh, Reg. No. 35,268/</u> Signature <u>Catherine C. Maresh</u> Typed or printed name <u>707.543.0221</u> Telephone number <u>November 14, 2006</u> Date </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p>			
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/674,296	Confirmation No.:	4107
Applicant	:	THORNTON, Ronan		
Filed	:	September 29, 2003		
TC/A.U.	:	3738		
Examiner	:	PRONE, Christopher D.		
Docket No.	:	P1818		
Customer No.	:	28390		
Title	:	LAMINATED DRUG-POLYMER COATED STENT WITH DIPPED AND CURED LAYERS		

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

In the Office Action dated August 15, 2006, claims 17-25, 28-38, 40, 41, 43-45, and 47 were rejected under 35 U.S.C. §102(b) as being anticipated by Fearnot (U.S. Patent No. 5,380,299), claims 26 and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fearnot in view of Guruwaiya (U.S. Patent No. 6,251,136), and claims 42 and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fearnot in view of Helmus et al. (U.S. Patent No. 5,447,724). Applicants respectfully submit that the rejections to the pending claims are clearly improper for the reasons discussed below, and respectfully request that the pending claims be allowed.

35 U.S.C. §102(b) REJECTION

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”
Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The rejection of claims 17-25, 28-35, 37, 38, 40, 41, 43-45, and

47 is improper because Fearnot does not disclose or even remotely suggest each and every feature of independent claims 17, 25, 35, and the claims that depend therefrom.

Independent claim 17 recites a drug-polymer coated stent that includes “a stent framework; a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer, and at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the at least one thin barrier layer includes a cured second polymer.”

As stated in Applicants’ own specification, “Curing, in the context of this specification, refers to either cross-linking or polymerization, or a combination thereof.” *See* specification at page 11, lines 4-6. In contrast, Fearnot merely discloses that the thrombolytic agent is dried after it has been applied to the base material. *See* Fearnot at col. 2, lns. 15-21. Although Fearnot discloses that the thrombolytic agent may be mixed with a polymer or a biologically derived material, no further details are given as to what happens to the mixture after it has been applied to the base material. *See, e.g.*, Fearnot at col. 2, lns. 21-25, and col. 4, lns. 16-22; *see also* Applicant’s Amendment filed July 12, 2005 at p. 8, lns. 16-19. Even if the polymer is dried just as the thrombolytic agent is dried, it does not necessarily follow that the polymer is cured – as defined by Applicants’ specification.

As such, Fearnot does not disclose – either expressly or inherently – a plurality of thin drug-polymer layers that include a first therapeutic agent and a cured first polymer, and at least one thin barrier layer that includes a cured second polymer, as recited by claim 17.

Moreover, Fearnot does not disclose or suggest at least one thin barrier layer positioned between one or more thin drug-polymer layers, as recited by claim 17. Although Fearnot teaches that multiple layers of the thrombolytic agent may be applied to the base material, Fearnot does not disclose or remotely suggest that any such layers are a barrier layer that includes a cured second polymer, as recited by claim 17. *See, e.g.*,

Fearnot at col. 4, lns. 12-16; *see also* Applicants' Amendment filed June 12, 2006 at p. 8, ln. 23 – p. 9, ln. 19.

Accordingly, Applicants respectfully submit that claim 17 and the claims that depend from claim 17 are patentable over Fearnot, and respectfully request that the rejection to claims 17-24, 41, and 43 be withdrawn.

Independent claim 25 recites a system for treating a vascular condition that includes, *inter alia*, a coated stent coupled to a catheter. As recited by claim 25, the coated stent includes a stent framework and a laminated drug-polymer coating disposed on the stent framework. As further recited by claim 25, “the laminated drug-polymer coating including a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the thin barrier layer includes a cured second polymer.”

Fearnot is discussed above. Because Fearnot does disclose, either expressly or inherently, a plurality of thin drug-polymer layers that include a cured first polymer and at least one thin barrier layer that includes a cured second polymer, Fearnot does not anticipate claim 25.

Accordingly, Applicants respectfully submit that claim 25 and the claims that depend from claim 25 are patentable over Fearnot, and respectfully request that the rejection to claims 25, 28-34, 44, and 45 be withdrawn.

Independent claim 35 recites a method of treating a vascular condition that includes, *inter alia*, inserting a drug-polymer coated stent within a vessel of a body. As recited by claim 35, the drug-polymer coated stent includes “a laminated drug-polymer coating having a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the thin barrier layer includes a cured second polymer.” As further recited by claim 35, “the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation.” Fearnot does not disclose or suggest all of the features of claim 35.

As discussed above, Fearnot does not disclose that the polymer that may be used with the thrombolytic agent is cured – either expressly or inherently. As discussed above, even if the polymer is dried just as the thrombolytic agent is dried, it does not necessarily follow that the polymer is cured – as defined by Applicants’ specification. Moreover, Fearnot does not disclose or suggest that the first polymer is cured with thermal activation, electrical activation, or ionizing irradiation, as recited by claim 35.

Accordingly, Applicants respectfully submit that claim 35 and the claims that depend from claim 35 are patentable over Fearnot, and respectfully request that the rejection to claims 35-38, and 47 be withdrawn.

35 U.S.C. §103(a) REJECTIONS

In order to make a *prima facie* case of obviousness under § 103(a), all of the *claimed* elements of the invention must be taught or suggested by the prior art. *See* MPEP § 2143.03. As discussed above, independent claims 17, 25, and 35 and the claims that depend from claims 17, 25, and 35 are patentable over Fearnot, because Fearnot does not disclose or suggest each and every feature of the claims. Neither Guruwaiya nor Helmus et al. cures the deficiencies of Fearnot.

Guruwaiya discloses a stent (16) that is covered with a base coat (18) on which a pharmacological agent (20) is applied. *See* Guruwaiya at col. 3, lns. 38-43. A continuous membrane (22) encapsulates the entire device. *See* Guruwaiya at col. 3, lns. 43-45. In an embodiment, the ethylene vinyl alcohol forms the desired membrane upon curing. *See* Guruwaiya at col. 4, lns. 35-36. The pharmacological agent and membrane are clearly separate layers. Hence, Guruwaiya does not disclose or suggest a stent having a drug-polymer layer that includes a therapeutic agent and a cured polymer, as recited by the claims. Moreover, Guruwaiya does not disclose or suggest a barrier layer that is positioned between one or more drug-polymer layers, as recited by the claims.

Helmus et al. discloses a medical instrument substrate (18) on which a polymer release coating (16) is bonded. *See* Helmus et al. at col. 5, lns. 20-36. The polymer release coating (16) includes a polymer surface layer (20) and a reservoir portion (24). *See* Helmus et al. at col. 5, lns. 20-36. Helmus et al. does not disclose or suggest a barrier

layer that is positioned between one or more drug-polymer layers, as recited by the claims.

Accordingly, Applicants respectfully submit that dependent claims 26 and 27 are patentable, because the combination of Fearnot and Guruwaiya does not disclose or suggest each and every feature of claims 26 and 27. Likewise, dependent claims 42 and 46 are also patentable because the combination of Fearnot and Helmus et al. does not disclose or suggest each and every feature of claims 42 and 46.

CONCLUSION

Applicants respectfully submit that all of the pending claims are patentable over the prior art of record, because the prior art of record – either alone or in combination – clearly does not disclose or suggest each and every feature of each and every pending claim. Accordingly, Applicants respectfully request that the rejections to claims be withdrawn.

Respectfully submitted,

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